UNITED STATES DISTRICT COURT EASTERN DISTRICT OF TEXAS MARSHALL DIVISION

CENTOCOR, INC. and, NEW YORK UNIVERSITY,)))
Plaintiffs,))
) Civil Action No. 2:07CV139 (TJW)
ABBOTT LABORATORIES, ABBOTT)) Jury
BIORESEARCH CENTER, INC., and ABBOTT BIOTECHNOLOGY LTD.)) Judge Ward)
Defendants.)))

ANSWER TO SECOND AMENDED COMPLAINT AND COUNTERCLAIMS OF ABBOTT LABORATORIES, ABBOTT BIORESEARCH CENTER, INC., AND ABBOTT BIOTECHNOLOGY LTD.

Abbott Laboratories ("Abbott Labs"), Abbott Bioresearch Center, Inc. ("ABC"), and Abbott Biotechnology Ltd. ("ABL") (collectively "Abbott") by their undersigned attorneys, hereby respond to the Second Amended Complaint of Centocor, Inc. ("Centocor") and New York University ("NYU") (collectively "Plaintiffs") as follows:

PARTIES

- 1. Abbott is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 1 of the Second Amended Complaint.
- 2. Abbott is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 2 of the Second Amended Complaint.
- 3. Abbott Labs admits that Abbott Labs is a corporation organized and existing under the laws of the State of Illinois with a place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

- 4. ABC admits that it is a wholly owned subsidiary corporation of Abbott Labs that is organized and existing under the laws of the State of Delaware with a place of business at 100 Research Drive, Worcester, Massachusetts 01605.
- 5. ABL admits that it is a wholly owned subsidiary corporation of Abbott Labs that is organized and existing under the laws of Bermuda with a place of business at Carr #2 Km. 59.2, Segundo Piso, Barceloneta, Puerto Rico 00617.

JURISDICTION AND VENUE

- 6. Paragraph 6 of the Second Amended Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, Abbott admits that Plaintiffs' claims purport to arise under the Patent Laws of the United States, Title 35 of the United States Code.
- 7. Paragraph 7 of the Second Amended Complaint contains conclusions of law to which no response is required.
- 8. Paragraph 8 of the Second Amended Complaint contains conclusions of law to which no response is required.

COUNT FOR PATENT INFRINGEMENT

9. Paragraph 9 of the Second Amended Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, Abbott denies that United States Patent No. 7,070,775 (the "'775 patent") entitled "Recombinant A2-Specific TNFα Specific Antibodies" was duly and legally issued. Abbott admits that the '775 patent states on its face that it was issued by the United States Patent and Trademark Office on July 4, 2006. Abbott admits that the '775 patent states on its face that Centocor and NYU are assignees. Abbott further admits that Exhibit 1 to the Second Amended Complaint appears to be a copy of the '775

patent. Abbott is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 9 of the Second Amended Complaint.

- 10. Paragraph 10 of the Second Amended Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, Abbott denies that United States Patent No. 7,276,239 (the "'239 patent") entitled "Recombinant A2-Specific TNFα-Specific Antibodies" was duly and legally issued. Abbott admits that the '239 patent states on its face that it was issued by the United States Patent and Trademark Office on October 2, 2007. Abbott admits that the '239 patent states on its face that Centocor and NYU are assignees. Abbott further admits that Exhibit 2 to the Second Amended Complaint appears to be a copy of the '239 patent. Abbott is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 10 of the Second Amended Complaint.
- 11. Paragraph 11 of the Second Amended Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, Abbott denies that either the '775 patent or the '239 patent claims antibodies and antibody fragments that bind Tumor Necrosis Factor- α ("TNF- α "). Abbott is without knowledge or information sufficient to form a belief as to the remaining allegations contained in paragraph 11 of the Second Amended Complaint.
- 12. Paragraph 12 of the Second Amended Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, Abbott admits that Abbott, either directly or through one of its subsidiaries and/or affiliates, makes, uses, offers for sale, and/or sells in, or imports into, the United States, adalimumab under the trade name Humira[®] Abbott admits that adalimumab is a fully human monoclonal antibody that binds TNF-

- α. Abbott admits the remaining allegations contained in paragraph 12 of the Second Amended Complaint.
- 13. Paragraph 13 of the Second Amended Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, Abbott denies the allegations contained in paragraph 13 of the Second Amended Complaint.
- 14. Paragraph 14 of the Second Amended Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, Abbott denies the allegations contained in paragraph 14 of the Second Amended Complaint.
- 15. Paragraph 15 of the Second Amended Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, Abbott denies the allegations contained in paragraph 15 of the Second Amended Complaint.
- 16. Paragraph 16 of the Second Amended Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, Abbott denies the allegations contained in paragraph 16 of the Second Amended Complaint.

PRAYER FOR RELIEF

Abbott denies that Plaintiffs are entitled to any relief whatsoever.

AFFIRMATIVE DEFENSES

First Affirmative Defense

Plaintiffs are not entitled to any relief against Abbott because Abbott has not infringed and is not infringing (either directly, by inducement, or contributorily) any valid and enforceable claim of either the '775 patent or the '239 patent, nor is it doing so willfully.

Second Affirmative Defense

The claims of both the '775 patent and the '239 patent are invalid for failing to meet one

or more of the requisite conditions for patentability specified by 35 U.S.C. § 101 et seq.

Third Affirmative Defense

Plaintiffs are estopped from asserting both the '775 patent and the '239 patent against Abbott.

Fourth Affirmative Defense

Plaintiffs are not entitled to relief against Abbott because both the '775 patent and the '239 patent are unenforceable because of laches, unclean hands, and/or other applicable equitable doctrines.

Fifth Affirmative Defense

The claims of both the '775 patent and the '239 patent are unenforceable based upon the doctrine of prosecution laches.

Sixth Affirmative Defense

Plaintiffs have failed to state a claim upon which relief can be granted for willful infringement.

Seventh Affirmative Defense

An arbitration award precludes Plaintiffs' infringement claims with respect to at least some of Abbott's activity relating to adalimumab/Humira[®].

Eighth Affirmative Defense

Abbott has a license to the '775 and the '239 patents for at least some of its activity relating to adalimumab/Humira[®].

Ninth Affirmative Defense

Claim or issue preclusion applies to Plaintiffs' infringement claims with respect to at least some of Abbott's activity relating to adalimumab/Humira[®].

Tenth Affirmative Defense

Abbott has a right to arbitrate one or more of its defenses.

COUNTERCLAIMS

Counterclaim Plaintiffs Abbott Laboratories ("Abbott Labs"), Abbott Bioresearch Center, Inc. ("ABC"), and Abbott Biotechnology Ltd. ("ABL") (collectively "Abbott") for their counterclaims against Counterclaim Defendants Centocor, Inc. ("Centocor") and New York University allege as follows:

Parties

- 1. Counterclaim Plaintiff Abbott Labs is a corporation organized under the laws of the State of Illinois with a place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064.
- 2. Counterclaim Plaintiff ABC is a wholly owned subsidiary corporation of Abbott Labs that is organized and existing under the laws of the State of Delaware with a place of business at 100 Research Drive, Worcester, Massachusetts 01605.
- 3. Counterclaim Plaintiff ABL is a wholly owned subsidiary corporation of Abbott Labs that is organized and existing under the laws of Bermuda with a place of business at Carr #2 Km. 59.2, Segundo Piso, Barceloneta, Puerto Rico 00617.
- 4. Counterclaim Defendant Centocor alleges that it is a corporation organized under the laws of the Commonwealth of Pennsylvania with its principal place of business at 800/850 Ridgeview Drive, Horsham, Pennsylvania 19044.
- 5. Counterclaim Defendant New York University alleges that it is a research university organized as a corporation under the laws of the State of New York and having a place of business at 70 Washington Square South, New York, New York 10012.

Jurisdiction and Venue

- 6. This is a counterclaim for a declaration of noninfringement, invalidity, and unenforceability of the claims of the '775 and the '239 patents. These counterclaims seek declaratory judgments pursuant to 28 U.S.C. §§ 2201 and 2202.
- 7. To the extent this Court has subject matter jurisdiction over the claims brought by Centocor and New York University in this action, it also has subject matter jurisdiction over Abbott's counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a) and Title 35 of the United States Code.
- 8. Given that Centocor and New York University (hereinafter collectively "Counterclaim Defendants") have asserted the '775 patent and the '239 patent against Abbott in this action, an actual case or controversy exists between the parties.

Background

- 9. Counterclaim Defendants have asserted that they own and/or license the '775 patent and the '239 patent, that Abbott infringes the '775 patent and the '239 patent, and that Abbott's infringement is willful.
- 10. Abbott Labs is a global, broad-based health care company devoted to discovering new medicines, new technologies and new ways to manage health. Its products span from nutritional products and laboratory diagnostics through medical devices and pharmaceutical therapies.
- 11. Abbott Labs has marketed and sold the biologic therapy adalimumab in the United States, under the trade name Humira[®], since the therapy was approved by the United States Food and Drug Administration ("FDA") in 2002. Humira[®] is approved as a treatment for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, plaque psoriasis and juvenile idiopathic arthritis.

- 12. Counterclaim Defendants filed the application that led to the issuance of the '775 patent on July 18, 2002.
- 13. Counterclaim Defendants have asserted the '775 patent against Abbott, apparently alleging that the scope of the '775 patent's claims encompasses adalimumab/Humira®.
- 14. Counterclaim Defendants filed the application that led to the issuance of the '239 patent, which is a divisional of the July 18, 2002 application, on December 20, 2005.
- 15. Counterclaim Defendants have asserted the '239 patent against Abbott, apparently alleging that the scope of the '239 patent's claims encompasses adalimumab/Humira[®].

<u>First Counterclaim</u> (Non-Infringement of the '775 patent)

- 16. Abbott repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
 - 17. Abbott does not infringe any valid and enforceable claim of the '775 patent.
- 18. To resolve the legal and factual questions raised by Abbott and to afford relief from the uncertainty and controversy which Abbott's accusations have precipitated, Abbott is entitled to a declaratory judgment that Abbott does not infringe on any valid and enforceable claim of the '775 patent.

Second Counterclaim (Invalidity of the '775 patent)

- 19. Abbott repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
 - 20. One or more claims of the '775 patent are invalid under 35 U.S.C. § 101 et seq.
- 21. To resolve the legal and factual questions raised by Abbott and to afford relief from the uncertainty and controversy which Abbott's accusations have precipitated, Abbott is entitled to a declaratory judgment that one or more of the claims of the '775 patent are invalid.

<u>Third Counterclaim</u> (Unenforceability of the '775 patent)

- 22. Abbott repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 23. One or more claims of the '775 patent are unenforceable under the doctrine of prosecution laches.
- 24. To resolve the legal and factual questions raised by Abbott and to afford relief from the uncertainty and controversy which Abbott's accusations have precipitated, Abbott is entitled to a declaratory judgment that one or more of the claims of the '775 patent are unenforceable.

Fourth Counterclaim (Non-Infringement of the '239 patent)

- 25. Abbott repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
 - 26. Abbott does not infringe any valid and enforceable claim of the '239 patent.
- 27. To resolve the legal and factual questions raised by Abbott and to afford relief from the uncertainty and controversy which Abbott's accusations have precipitated, Abbott is entitled to a declaratory judgment that Abbott does not infringe on any valid and enforceable claim of the '239 patent.

Fifth Counterclaim (Invalidity of the '239 patent)

- 28. Abbott repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
 - 29. One or more claims of the '239 patent are invalid under 35 U.S.C. § 101 et seq.

30. To resolve the legal and factual questions raised by Abbott and to afford relief from the uncertainty and controversy which Abbott's accusations have precipitated, Abbott is entitled to a declaratory judgment that one or more of the claims of the '239 patent are invalid.

<u>Sixth Counterclaim</u> (Unenforceability of the '239 patent)

- 31. Abbott repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 32. One or more claims of the '239 patent are unenforceable under the doctrine of prosecution laches.
- 33. To resolve the legal and factual questions raised by Abbott and to afford relief from the uncertainty and controversy which Abbott's accusations have precipitated, Abbott is entitled to a declaratory judgment that one or more of the claims of the '239 patent are unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Abbott requests entry of judgment in its favor and against Plaintiffs-Counterclaim Defendants as follows:

- A. Declaring that Abbott does not infringe any of the claims of the '775 patent;
- B. Declaring that all of the claims of the '775 patent are invalid;
- C. Declaring that all of the claims of the '775 patent are unenforceable;
- D. Declaring that Abbott does not infringe any of the claims of the '239 patent;
- E. Declaring that all of the claims of the '239 patent are invalid;
- F. Declaring that all of the claims of the '239 patent are unenforceable;
- G. Finding that this is an exceptional case under 35 U.S.C. § 285 and awarding Abbott the costs and expenses of this litigation, including reasonable attorneys' fees and disbursements; and

H. Awarding Abbott other such relief as is just and proper.

DEMAND FOR JURY TRIAL

Defendants and Counterclaim Plaintiffs demand a trial by jury on all issues so triable.

Dated: July 7, 2008

Respectfully submitted,

By: /s/ David J. Beck

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CERTIFICATE OF SERVICE

I hereby certify that counsel of record, who are deemed to have consented to electronic service in the above-referenced case, are being served this 7th day of July, 2008 with a copy of the above-document via the court's CM/ECF System per Local Rule CV-5(a)(3).

/s/ Michael E. Richardson Michael E. Richardson